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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/312,351

05/14/1999

JON A. WOLFF

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03/04/2009

MIRUS CORPORATION
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EXAMINER

VALENROD, YEVGENY

ART UNIT

PAPER NUMBER

1621

MAIL DATE

DELIVERY MODE

03/04/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 09/312,351	Applicant(s) WOLFF ET AL.	
	Examiner YEVEGENY VALENROD	Art Unit 1621	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 November 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 7, 8, 19 and 20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 7, 8, 19 and 20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The following is a non-final rejection in application # 09/312,351.

Remarks filed 11/20/08 have been fully considered by Examiner. Examiners reply to applicants' remarks and to the Declaration of Dr. Monahan follows the repeated text of the rejection of record.

Rejection of claims 19 and 20 under 35 USC 102(b) is withdrawn in view of applicants' remarks and Declaration of Dr. Monahan.

Maintained Claim Rejections - 35 USC § 102

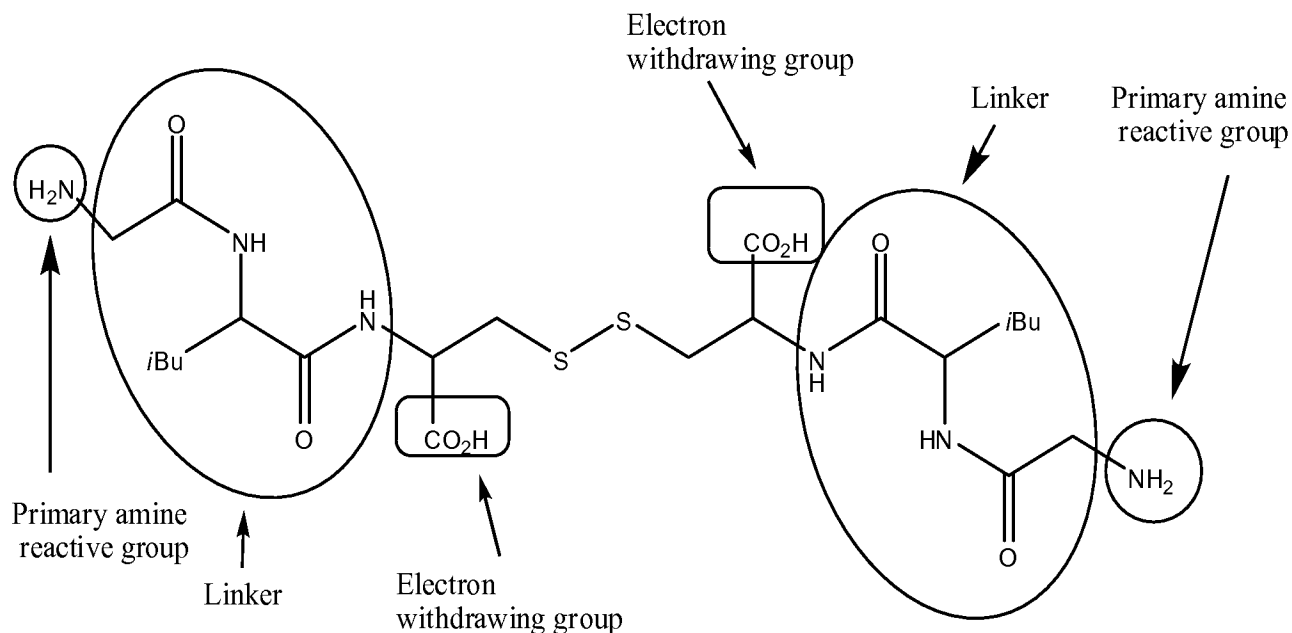
The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 7 and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Abderhalden, Emil et al. (Berichte der Deutschen Chemischen Gessellschaft, 1916, 49 2449-2473; CAS abstract, form here on D1, cited in the office action of 2/28/08).

D1 discloses the following compound (the groups as they relate to the instant claims are labeled by the Examiner):



All the structural limitations of claims 7, 8, 19 and 20 are met by the above compound. Since the compound meets all the structural limitations set forth in the instant claims, properties such as: disulfide bond not being cleaved more rapidly than oxidized glutathione is an inherent property of the above compound (claims 7, 8) and increase in pKa of at least one constituent thiols of the disulfide bond not greater than that of glutathione pKa (claims 19-20) are inherently possessed by the above compound.

Reply to applicants' remarks and to the Monahan Declaration

Applicant has argued that the compound above fails to meet the limitation directed to the disulfide bond being cleaved more rapidly than oxidized glutathione in physiological conditions or pKa of at least one of the constituent thiols being less than the glutathione pKa.

The Monahan Declaration presents evidence to support the argument that the thiol of the arts compound has a pKa value greater than that of glutathione. Because of the greater pKa value, Dr. Monahan concludes that the arts compound would not be cleaved more rapidly than oxidized glutathione.

Examiner respectfully disagrees with the applicants. While Dr. Monahan might be correct about difference in the pKa between the thiol of the art compound and glutathione, the difference in pKa can only be used to predict the relative rates of cleaving in unassisted, heterolytic fashion. However, if the cleaving is assisted by an enzyme, the relative rates need not be necessarily be the same, also if the cleaving is homolytic, the rates could be inversed from what the pKa values suggest. Since the claim is open to any kind of cleaving of the disulfide, the compound of Abderhalden is anticipatory to the instantly claimed compound because the compound meets all of the structural limitations.

New Claim Rejections - 35 USC § 102

Claims 7, 8, 19 and 20 rejected under 35 U.S.C. 102(b) as being anticipated by Hartter et al (Struc. Act. Nat. Pept., Proc. Fall Meet. Ges. Biol. Chem. (1981) meeting date 1979, 497-504; CAPLUS abstract is used in this rejection)

Hartter disclose the compound according to the instant claims (see sole compound in the abstract). Said compound comprises a disulfide bond, an electron withdrawing group (secondary amine on carbon 2 to the sulfur), a linker (amide and the carbon chain that follows it) and a reactive group (primary amine). Although the pKa of

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the resulting thiol is not disclosed, according to the Monahan Declaration, the pKa is expected to be about 7.27 (see example of Cystine-Cystine on page 3 of the declaration) which is lower than pKa of 8.9 for Glutathione (page 2 of the declaration).

Conclusion

Claims 7, 8, 19 and 20 are pending.

Claims 7, 8, 19 and 20 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yevgeny Valenrod whose telephone number is 571-272-9049. The examiner can normally be reached on 8:30am-5:00pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Daniel Sullivan can be reached on 571-272-0779. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Yevgeny Valenrod/

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